UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al., ex rel.* DAVID KESTER, Plaintiffs, - v - NOVARTIS PHARMACEUTICALS CORPORATION, *et al.,* Defendants.	:	11 Civ. 8196 (CM)(JMF) ECF Case

STATEMENT OF THE UNITED STATES IN SUPPORT OF ITS ELECTION TO FURTHER INTERVENE IN PART AS TO NOVARTIS

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TABLE OF CONTENTS

Pursuant to 31 U.S.C. § 3730(c)(3), and in accordance with Paragraph 8 of the Court's January 8, 2014 Unsealing Order (the "Unsealing Order"), [Dkt. 44], the United States ("Government"), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, respectfully submits this statement in support of its election to further against defendant Novartis Pharmaceuticals Corporation ("Novartis") in part.

PRELIMINARY STATEMENT

This case seeks to hold Novartis responsible under the False Claims Act ("FCA") for offering and giving kickbacks to specialty pharmacies to induce the pharmacies to recommend two Novartis drugs, Myfortic and Exjade, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"). With regard to Exjade, the Government initially intervened against Novartis only in relation to Novartis's kickback arrangement with one pharmacy, BioScrip, Inc.

Since that time, however, the Government has learned that "the scope of the alleged fraud is more extensive than [] originally anticipated." *U.S. ex rel. Hall v. Schwartzman*, 887 F. Supp. 60, 62 (E.D.N.Y. 1995). Specifically, based on discovery undertaken in litigation, information from relator's investigative efforts, and factual admissions made by former co-defendant Accredo Health Group ("Accredo") as part of its settlement, it now is clear to the Government that Novartis also unlawfully offered inducements to Accredo in return for recommending Exjade refills to patients. *See infra* at 3.

"Good cause," therefore, exists for the Government to further intervene and vindicate the public interest at trial. *See infra* at 6-8. Further, the Government's election will not result in any prejudice. The Government is intervening only as to an aspect of the relator's existing complaint, and is not seeking to bring any new claims. Further intervention thus will not affect the scope of discovery or trial. In that regard, the Government has advised all parties involved in the Myfortic/Exjade phase of the case about its election to further intervene, and no party has

stated any objection.[1]

RELEVANT BACKGROUND

A. The Government's Intervention and Declination Decisions and the Reservation to Later Intervene For Good Cause

This *qui tam* action was filed in November of 2011, when the relator asserted wide-ranging claims alleging that Novartis and a number of specialty pharmacies violated the FCA with respect to numerous drugs, including Myfortic, an immunosuppressant, and Exjad, an iron chelation drug. The Government investigated, focusing its initial investigation on Myfortic. In April 2013, the Government partially intervened as to Novartis, alleging that it had orchestrated a kickback scheme in the distribution of Myfortic in violation of the AKS. At that juncture, the Court partially maintained the seal to permit the Government to continue its investigation.

In October 2013, the Government further intervened against Novartis on relator's claims that Novartis had violated the AKS in its relationship with BioScrip for the distribution of Exjade. On January 6, 2014, the Government filed an amended complaint and intervened against Bioscrip for taking part in a kickback relationship with Novartis for Exjade. The Government also simultaneously (*i*) settled its claims against Bioscrip, (*ii*) declined to intervene against all other defendants named by the relator (*e.g.*, Accredo and CVS Caremark Corp.), and (*iii*) expressly reserved its right to further intervene in this case for good cause, at any time, as provided by 31 U.S.C. § 3730(b).

On January 8, 2014, this Court unsealed this matter, ordering, *inter alia*, that as to "the part of the action in which the Government has declined to intervene," the Government had "leave to order any deposition transcripts and is entitled to intervene in that part of the action, for good cause, at any time." Unsealing Order ¶ 8. Aa copy of this Order is attached as Exhibit A.

[1] One week ago–on April 23–the Government made Novartis aware of the plan to further intervene this week and asked whether Novartis consents. To date, Novartis has not responded.

B. New and Significant Evidence Uncovered in Discovery and the Government's Settlement and Intervention Against Accredo

After this action was unsealed in January 2014, relator continued to pursue his *qui tam* claims against Novartis and Accredo based on their conduct in relation to Exjade distribution. Through discovery, relator has obtained voluminous documents from Novartis and Accredo concerning their Exjade relationship that had *not* been produced in the pre-suit investigation (indeed, many of the key documents were not produced until February and March 2015). Relator also conducted depositions and numerous interviews of former Accredo employees.

Relator's energetic discovery efforts yielded new and significant information concerning Novartis's relationship with Accredo. Discovery revealed – take just a few examples – that:

- Starting in late 2007, Novartis persistently pressured Accredo – using control over patient referrals as leverage – to increase its Exjade refill rate by having additional nurse intervention with patients. To that end, Novartis made presentations to Accredo regarding how Novartis wanted Accredo to structure and sequence the nurse calls.[2]
- By July 2008, Novartis had succeeded on making Accredo revamp how its nurse(s) dealt with Exjade patients. But that did not stop Novartis from continuing to monitor Accredo. In early 2009, a Novartis marketing manager met with one of Accredo's Exjade nurses in person to discuss how that nurse handled calls with Exjade patients.
- The Exjade nurses at Accredo were directed to use – and did follow – call scripts that told patients it was "very important" to keep taking Exjade in order to "prevent the following complications … [including] stroke [] or death," but did not mention the serious adverse reactions – such as organ failure – associated with taking Exjade.
- Accredo managers set weekly Exjade shipment goals for its staff; and, as a former customer service representative ("CSR") testified at her deposition in late March 2015, the Exjade staff at Accredo understood that their managers derived the goals from the shipment targets that Novartis gave Accredo.

Based on the additional evidence obtained by the relator, the Government determined that a sufficient basis exists to intervene as to both Novartis and Accredo. Accredo decided to pursue settlement discussions in relation to the Exjade claims asserted against it. As result of

[2] Most of these facts also are set forth in the factual admissions that Accredo made in paragraphs 2.a – 2.t of its stipulation of settlement with the Government and relator.

those negotiations, Accredo agreed to a settlement with the Government and the relator under which it will pay $45 million to resolve the federal claims against it.[3] Indeed, earlier today, the Court so-ordered both the Government's request for leave to further intervene as to Accredo and the Stipulation and Order of Settlement and Dismissal as between the United States and Accredo (the "Accredo Stipulation"). A copy of this stipulation is attached as Exhibit B.

In its settlement stipulation, Accredo made numerous factual admissions, including certain admissions relating to, *inter alia*, Novartis's dissatisfaction with Accredo's "adherence" scores on the Novartis "scorecard"; Novartis's involvement regarding Accredo's implementation of nurse interventions; and Novartis's plans to reduce patients referrals to Accredo if it continued to lag behind other EPASS pharmacies' in terms of the adherence score. *See* Accredo Stipulation, ¶¶ 2.a–2.t. In addition, that stipulation also requires Accredo to cooperate fully and truthfully with the Government in terms of providing relevant documents and information and usingits best efforts to make available currently and former employees available for interviews and testimony. *See id*. ¶ 12.

ARGUMENT

POINT I

THE FALSE CLAIMS ACT EXPRESSLY PROVIDES THE GOVERNMENT WITH THE RIGHT TO FURTHER INTERVENE FOR GOOD CAUSE FOLLOWING AN INITIAL DECLINATION

The FCA provides that, even when the Government declines to intervene at the outset of a *qui tam* action, the Court may "permit the government to intervene at a later date upon a showing of good cause." 31 U.S.C. § 3730(c)(3). This provision reflects Congress's recognition that even when the United States is not litigating a specific FCA claim, it remains the real party in interest. The great majority of funds recovered even in a non-intervened *qui tam* case flow to the federal treasury, *see* id. § 3730(d); and the Government is bound by a judgment in a *qui tam*

[3] We understand that Accredo and the States are finalizing their proposed settlements.

case regardless of whether it intervenes, *see United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 936 (2009).

As legislative history shows, the FCA vests the Government with the power to later intervene in an initially declined case to ensure that it can effectively protect the public interest. *See* S. Rep. No. 345 at 26-27 (reprinted in 1986 U.S.C.C.A.N. at pp. 5266, 5291-92) (1986) (recognizing that not providing the Government with an opportunity to later intervene after an initial declination "could [] work to the detriment of the government's interests"). Further, although the FCA does not define "good cause" for intervention after an initial declination, courts – looking to the legislative history of § 3730(c)(3) – have uniformly held that the discovery of "new and significant evidence" is a basis for a finding of "good cause." *See, e.g., United States v. Aseracare Inc*., No. 2:12-CV-245-KOB, 2012 WL 4479123, at *2 (N.D. Ala. Sept. 24, 2012); *U.S. ex rel. Stone v. Rockwell Int'l Corp*., 950 F. Supp. 1046, 1048-49 (D. Colo. 1996); *U.S. ex rel. Tyson v. Amerigroup Illinois Inc*., 02 C 6074, 2005 WL 2667207, at *3 (N.D. Ill. Oct. 17, 2005). Prejudice to the defendant or a delay in the litigation also can be relevant – but not dispositive – factors in this analysis, *see*, *e.g.*, *Hall*, 887 F. Supp. at 62; *U.S. ex rel. Lam v. Tenet Healthcare Corp*., 481 F. Supp. 2d 689, 694 95 (W.D. Tex. 2007) (good cause exists even in the absence of "newly discovered evidence" because the Government's interest in intervention where it deems necessary outweighs prejudice to other parties), because, ultimately, "[w]hat is of paramount importance is the public interest." *Stone*, 950 F. Supp. at 1049.

POINT II

THE GOVERNMENT HAS GOOD CAUSE TO FURTHER INTERVENE AGAINST NOVARTIS

A. New and Significant Evidence Demonstrate That "Good Cause" Exists for the Government to Further Intervene Against Novartis

Litigation in this action has given the Government access to numerous pieces of new and significant evidence regarding how Novartis used patient referrals and related benefits to induce

Accredo to recommend Exjade refills. For example, as summarized above, discovery illustrates how, between late 2007 and July 2008, Novartis, by persistently exerting pressure on Accredo using Exjade patient referrals as leverage, succeeded in having Accredo implement a program of having a nurse contacting Exjade patients to encourage them to order refills as recommended by Novartis's marketing team. *See supra* at 3; *see also* Accredo Stipulation ¶¶ 2.h–2.j (admitting facts concerning pressure Novartis exerted on Accredo). Indeed, discovery confirms that, when the nurses at Accredo called Exjade patients, they were directed to, and did, follow call scripts that emphasized the importance of taking Exjade without disclosing the drug's very serious potential adverse reactions, such as organ failure. *See supra* at 3; *see also* Accredo Stipulation ¶ 2.q (admitting facts concerning the call script used after February 2010). Finally, discovery shows that Accredo not only had weekly Exjade shipment goals for its staff, but also derived those goals from the shipment targets that Novartis gave Accredo. *See supra* at 3.

These facts parallel key aspects of Novartis's kickback arrangement with BioScrip – both in terms of how Novartis leveraged its control over Exjade patient referrals to induce the pharmacy to recommend refills and how the recommendations were made to Exjade patients – that the Government identified in its pre-suit investigation and that form the basis of the Exjade claims already asserted in the Government's pleadings. *See U.S. ex rel. Kester v. Novartis*, 23 F. Supp. 3d 242, 247-48 (S.D.N.Y. 2014) ("*Kester I*") (summarizing the gravamen of the Government's allegations concerning Novartis's kickback arrangement with BioScrip). In short, evidence that Novartis engaged in similar conduct in its Exjade relationship with Accredo is the type of "new and significant evidence" constituting good cause under 31 U.S.C. § 3730(c)(3). *Amerigroup*, 2005 WL 2667207, at *3 ("good cause" present for intervention after declining three years earlier based on evidence obtained by the relator during discovery); *Hall*, 887 F. Supp. at 62 ("good cause" exists after the Government "uncovered information suggesting that

the scope of the alleged fraud is more extensive than it originally anticipated"); *see also Aseracare Inc*., 2012 WL 4479123, at *1-2.

B. As the Real Party in Interest, the Government Is Entitled to Vindicate the Public Interest at Trial

Although a *qui tam* relator may – as relator did here – bring a claim on behalf of the Government under the FCA, the Government always "is the real party in interest." *U.S. ex rel. Kester v. Novartis*, 43 F. Supp. 2d 332, 358 (S.D.N.Y. 2014) ("*Kester IV*") (quoting *U.S. ex rel. Kreindler v. United Techs. Corp*., 958 F.2d 1148, 1154 (2d Cir. 1993)). The relator, moreover, is not afforded all the rights and protections available to the Government. *See, e.g., Eisenstein*, 556 U.S. at 932-33 (relator not entitled to the Government's 60-day period to file an appeal because "[t]he United States is a 'party' to a privately filed FCA action *only if it intervenes* in accordance with the procedures established by federal law) (emphasis added). Further, the Government is in the best position to pursue claims consistent with public policy and to articulate its views of the relevant laws, rules, and policies. Thus, the FCA's intervention for "good cause" provision reflects Congress's judgment that it is ultimately the Government's role and responsibility – when the Government deems it appropriate – to litigate and try a FCA case so as to vindicate the public interest and protect the public fisc.

Here, the Government has concluded, after reviewing newly discovered evidence and negotiating a settlement with Accredo, that it should intervene on the claims against Novartis based on the kickback arrangement it had with Accredo in relation to Exjade. Further, the Court has scheduled the trial of the Myfortic/Exjade part of the case for November 2. Accordingly, the Government is entitled to speak for itself – and on behalf of the public – at trial.

C. No Prejudice Will Result from The Government's Election

As noted above, and as the Government has advised the parties in the Myfortic/Exjade part of this case, the Government is not amending its complaint in connection with this partial

intervention. The election by the Government to further intervene against Novartis also will not affect the scope or duration of discovery or delay or lengthen the trial (indeed, the so-ordered settlement this week among the Government, relator, and Accredo likely will shorten the trial). Thus, there is no prejudice to any party; and, unsurprisingly, no party has voiced an objection after being notified of the Government's plan to further intervene in part. *See generally Hall*, 870 F. Supp. at 62 (recognizing that "the broadening of discovery is generally not a sufficient basis to deny intervention absent a showing of undue prejudice"); *Aseracare Inc.*, 2012 WL 4479123, at *2 (overruling defendants' objection that "good cause" intervention was untimely because it would require additional discovery).

CONCLUSION

For the reasons set forth above, we respectfully submit that good cause exists for the Government to further intervene in part against Novartis.

Dated: April 30, 2015
New York, New York

Respectfully submitted,

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